Paul Thompson Friday, June 05, 2009

Health Devices Alerts

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Accession Number: A12333 **High Priority**

Last Updated: Thursday, June 4, 2009
Broadcast Date: Friday, June 5, 2009

Radiometer—Waste Bottles Used with Series ABL700 and Series ABL800 Analyzers: Vent Holes May Be Blocked, Potential for Waste Material to Leak from Bottle and/or Analyzer

Source Document(s):
20090420RadiometerWasteBottlesMfr.pdf
20090430RadiometerWasteBottlesBfArM.pdf
20090602RadiometerWasteBottlesBfArM.PDF

UMDNS Device Term(s): Analyzers, Laboratory, Blood Gas/pH/Electrolyte/Metabolite [18-619];

Waste Receptacles [14-424]

Product Identifier:

Expand identifier information

Waste Bottles:	Product Nos.:	Lot Nos.:	Used with the following Analyzers:
(1) Model D512	(1) 905-590	(1) WR-01, WR-02, WR-03, WS-01, WS-02, WS-	(1) Series ABL700

Geographic Regions: Worldwide

Manufacturer: Radiometer A/S [139324], Akandevej 21, DK-2700 Bronshoj, Denmark

Problem: In an April 30, 2009, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Radiometer states that the vent holes on the above waste bottles were closed during the production process, potentially causing an overpressure condition to be created in the waste bottle and the analyzer. The overpressure condition may cause the waste bottle to have an abnormal shape (it appears bloated). When removing the waste bottle from the analyzer, waste material may leak from both the analyzer and the bottle.

Regulatory Agency:	Designation:
German Federal Institute for Drugs and Medical Devices (BfArM)	Reference No. 1630/09

Action Needed: Verify that you have received the April 30, 2009, Urgent Field Safety Notice letter and fax form from Radiometer. Identify, isolate, and discard any affected product in your inventory. Complete the fax form, and return it to Radiometer at the number on the form. The firm will arrange for product replacement. If urgent delivery of replacement bottles is required, contact your Radiometer local representative. If you suspect that a waste bottle that has already been installed on an analyzer has created an overpressure condition, Radiometer recommends performing the following:

(1) Follow legal requirements and local rules for safe work practices and wear suitable protection gear (e.g., gloves, face protection, protective body clothing).

(2) Remove the cover over the rinse and waste bottles.

(3) Remove the rinse bottle.

(4) Cover the joint between the waste bottle and the analyzer with a cloth to limit the leak.

(5) Pull the waste bottle back approximately 1 cm, and hold it in this position for 5 sec to allow the overpressure to equalize.

(6) Pull the waste bottle completely out, and discard it.

(7) Wipe off waste stains, if any.

(8) Follow legal requirements and local rules for disposal of infectious waste.

For Further Information:		
Geographic Location:	Contact:	Web Site:
Worldwide	Radiometer local representative	Click here

Source:

- Germany. Federal Institute for Drugs and Medical Devices. Replacement of wast [*sic*] bottles for ABL700 and ABL800 analysers, Radiometer [online]. 2009 Jun 2 [cited 2009 Jun 2]. Available from Internet: Click here.
- Manufacturer.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

Suggested Distribution: Clinical Laboratory/Pathology, Clinical/Biomedical Engineering, CSR/Materials Management

Verification History: Alert Confirmed by Non-U.S. Regulatory Agency[6/2/2009 2:06:00 PM]; Alert Confirmed by Mfr./Dist. [6/4/2009 9:23:07 AM]; Fully verified[6/4/2009 9:23:10 AM]

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